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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,730	03/03/2004	Makoto Ozeki	1422-0625P	2621
2292	7590	11/30/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			CLAYTOR, DEIRDRE RENEE	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/790,730

Applicant(s)

OZEKI ET AL.

Examiner

Renee Claytor

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
4a) Of the above claim(s) 1-3 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 4 and 5 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/10/2004.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group III, with traverse, is hereby acknowledged. Claims 4-5 read on the elected group and are being examined on their merits herein. Claims 1-3 do not read on the elected species and are being withdrawn from consideration. Applicant's argument that there is no undue burden to search all of the claims is not found persuasive. As was stated in the Election/Restriction requirement dated on 9/26/2006, Groups I and II are distinct in that Group I is drawn to a pharmaceutical composition containing pharmaceutically acceptable ingredients for administration and Group II is drawn to a food or beverage that can include anything from teas to breads. Both of these groups are distinct from Group III in that Group III is the process of use of the product of Groups I or II. Therefore, the election requirement is deemed proper and made **FINAL**.

The present application is not entitled to priority of Japanese Application No. 2001-253740 filed on 8/24/2001 due to the fact that the priority document was filed more than one year before the present application.

Objections

Claims 4 and 5 objected to because of the following informalities: the claims refer back to a composition of claims that are withdrawn. Appropriate correction is required.

Claim Rejections – 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for decreasing the symptoms of the mood disorder (depression), does not reasonably provide enablement for the **prevention** of the symptoms of depression. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims 4 and 5 are drawn to "a method for ameliorating or preventing mood disorders or a symptom of mood disorders, comprising administration of a theanine composition".

(2) The state of the prior art: The state of the art regarding treating mood disorders is relatively high. However, the state of the art for prevention of mood disorders is underdeveloped.

(3) The relative skill of those in the art: The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art: The skilled artisan would view that the treatment to prevent mood disorders in a human or animal is totally, absolutely, or highly unpredictable.

(5) The breadth of the claims: The claims 4 and 5 embrace ameliorating or preventing mood disorders or symptoms of mood disorders comprising administration of a composition comprised of theanine.

(6) The amount of guidance or direction presented: In the instant case, no working examples are presented in the specification as filed showing how to prevent mood disorders or symptoms of mood disorders. Note that lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP § 2164. The specification on pages 22-30 details studies performed in patients clinically diagnosed with mood disorder, that were administered compositions comprised of theanine and the therapeutic effects were assessed according to the Hamilton scale. As a result of treatment, the overall average score on

the Hamilton scale was decreased following theanine treatment proving that theanine was an effective treatment for mood disorder but not for the prevention of mood disorders.

(7) The presence or absence of working examples: Applicant does not provide any working examples for the prevention of mood disorders.

(8) The quantitation of experimentation necessary: Claims 4 and 5 read on the prevention of mood disorder or symptoms of mood disorders. As discussed above, the specification fails to provide sufficient support for completely protecting against mood disorder. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. *Genetech*, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections – 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Makoto et al. (JP Application # 2001-253740).

Makoto et al. teach a method for treating mood disorders comprising administration of theanine in which theanine is contained in food or drugs (meeting the limitations of claims 4 and 5; paragraph 011, 0012 and claims). It is taught that

theanine improves the condition of depression among the mood disorders as assessed by the Hamilton scale (further meeting the limitation of claim 5; paragraph 0012 and 0041).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blum et al. (U.S. Patent 6,132,724) in view of Kent et al. (J Affect Dis. 73 (2003); 211-221).

Blum et al. teach a method of treating attention deficit hyperactivity disorder (ADHD) with theanine (Col. 22, lines 13-18; Col. 75, Table 20).

Blum et al. do not teach a method for treating mood disorders with theanine.

Kent et al. review research that ADHD and mood disorders (bipolar disorder) share symptoms (see Section 3 and Table 1). It is further taught that studies reporting high rates of ADHD in children with bipolar disorder in children (see Section 4.3).

Accordingly, it would be obvious to one having ordinary skill in the art at the time of the invention to combine the teachings of Kent et al., which teaches comorbidity of ADHD and bipolar disorder, with Blum et al., which teaches treating ADHD with theanine. One would have been motivated to treat mood disorders with theanine because the prior art teaches that ADHD and mood disorder share symptomatology. By administering theanine to a patient diagnosed with ADHD and bipolar disorder, a

reasonable expectation of success of alleviation of symptoms would be expected since the two conditions share symptomatology.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 4-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 11-14, 16, 22-23 of copending Application No. 10/311,972. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of ameliorating mood disorders comprising administration of theanine while the claims of Application No. 10/311,972 are drawn to a method of suppressing psychological influences which negatively act during working. Although the claims of

Application No. 10/311,972 do not specifically recite mood disorders as a psychological influence, it would be obvious to one having ordinary skill in the art that a mood disorder is a type of psychological influence and one would be motivated to treat with theanine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 4-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/343/931. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of ameliorating mood disorders comprising administration of theanine while the claims of Application No. 10/343,931 are drawn to a method of ameliorating attention-deficit hyperactivity disorder comprising the administration of theanine. Although the claims of Application No. 10/343, 931 are drawn specifically to attention-deficit hyperactivity disorder, it would be obvious to one having ordinary skill in the art that attention-deficit hyperactivity disorder and mood disorders are both types of psychological disorders and one would be motivated to treat both with theanine.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor



**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**